

Transcript of TETANUS AND DIPHTHERIA TOXOIDS AND ACELLULAR  
PERTUSSIS VACCINE (Tdap) VACCINE SEGMENT of Immunization Update  
2006, August 10, 2006.

This podcast is presented by The Centers for Disease Control and  
Prevention. CDC - Safer. Healthier. People.

JOE WASHINGTON:

Welcome back to Immunization Update 2006. Joining us for this  
part of the program is Donna Weaver. Donna Weaver is a nurse  
educator in the National Immunization Program at CDC. Ms. Weaver  
has a masters degree in nursing, and has been working in  
immunization programs since 1996.

Pertussis has been a source of frustration for both public  
health and private providers for several years. The disease is  
difficult to diagnose, difficult to treat, and seems to be  
increasing despite our best efforts to control it. New vaccines  
give us a new tool in our ongoing battle against pertussis.  
Donna will begin our discussion. Donna?

DONNA WEAVER:

Thank you Joe. In this segment of the program we are going to  
discuss pertussis and acellular pertussis vaccines for  
adolescents and adults. These vaccines, which we will refer to  
as TDAP, have been available now for more than a year. We  
discussed the use of TDAP among adolescents on two prior  
broadcasts. In addition, an ACIP statement addressing the use of  
TDAP among adolescents was published in March 2006. We hope you  
have already familiarized yourself with this important and  
comprehensive document. If you have not, we will put a link to  
it on our broadcast updates and resources web page. Today we  
would like to focus on the second front in our new war on  
pertussis - the use of TDAP among adults. ACIP finalized these  
recommendations in June, and they will not be published until  
later in 2006. But we would like to familiarize you with these  
new recommendations since some of them apply to you personally.  
We would like to begin with a brief review of the recent  
epidemiology of pertussis, which forms the basis of the new  
recommendations. Bill is in the Interactive Data Center with  
that part of the presentation.

DR. BILL ATKINSON:

Thank you Donna. Despite very effective efforts to raise  
pertussis vaccination levels among children, reported pertussis  
cases have risen steadily for the past 20 years. In this graphic  
we will show the number of cases of pertussis reported by year

since 1980. Years are shown on the X axis and the number of cases are here on the Y axis. Reported pertussis was at its lowest point in the United States in 1976. In 1980 one thousand 7 hundred cases and 11 deaths were reported. From 2 thousand to 4 thousand cases were reported annually for the next decade. During the 1990s reported cases gradually increased, punctuated with peaks every 3 to 5 years. About 8 thousand cases were reported in 2000. A dramatic increase in reported cases has occurred since 2000. 11 thousand cases were reported in 2003, and more than 25 thousand in both 2004 and 2005, the highest annual totals since 1959. Pertussis vaccination rates have increased substantially since 1996.

So why has the number of reported cases not declined? The answer to this question may be in WHO is being reported with pertussis. This graph shows the number of pertussis cases reported by age group and year since 1990. This is a stacked line graph with the total number of cumulative cases indicated by each line. Children younger than 11 years are shown in red. Cases among adolescents 11 through 18 years of age shown in blue, and adults 19 and older are indicated by the green line. In the early 1990s, most cases were reported among children. Adults and adolescents together accounted for less than 20% of the 4 thousand pertussis cases reported in 1990. During the late 1990s the number of cases reported among children was stable. But an increasing proportion of cases were being reported among both adolescents and adults. Since 2000 there has been a substantial increase in reported cases among adolescents and adults. In 2005 more than 14 thousand pertussis cases were reported among adolescents and adults, accounting for almost two thirds of all reported cases.

The number and proportion of reported pertussis cases among adolescents and adults has increased significantly in the last decade. This increase could be partly due to changes made in the surveillance definition of pertussis. It could also be due to increased recognition and diagnosis of pertussis among older age groups. One factor that may be contributing to the rise in pertussis among older children and adults is waning vaccine induced immunity. Protection declines as you get further away from the time you had your last dose. After 5 to 10 years, vaccine induced immunity is probably minimal. At this point, even vaccinated persons may become infected and develop mild or undiagnosed disease, which could then be transmitted to incompletely vaccinated infants. Back to you, Donna.

DONNA WEAVER:

Vaccination is the most effective strategy to reduce the burden of pertussis. While there are common features, ACIP decided to address vaccination of adolescents and adults separately. As we mentioned earlier the adolescent recommendations were published in March 2006. The adult TDAP recommendations should be published later in 2006. The objective of these new recommendations is to protect vaccinated adolescents and adults against pertussis. A secondary objective is to reduce the reservoir of *Bordetella pertussis* in the population, and thereby potentially reduce the incidence of pertussis in other age groups, particularly infants. Two manufacturers have licensed TDAP vaccines that contain acellular pertussis antigens. Both vaccines contain a reduced quantity of pertussis antigen compared with pediatric pertussis vaccines. The quantity of tetanus and diphtheria toxoids is similar to available adult TD formulations. Boostrix TDAP vaccine is manufactured by GlaxoSmithKline. It was licensed May 3, 2005 for use as a single dose in persons 10 through 18 years of age. ADACEL TDAP vaccine is manufactured by sanofi pasteur. Adacel was licensed June 10, 2005 for use as a single dose in persons 11 through 64 years of age. Note that only Adacel is approved for adults 19 through 64 years of age. Neither vaccine is approved by FDA for persons younger than 10 years or older than 64 years.

A few general principles apply to the use of TDAP and Td in adolescents and adults. ACIP has not stated a preference for one brand of TDAP, EXCEPT that each vaccine should be used within its approved age range. ACIP does not recommend off-label use of these vaccines outside their approved age ranges. In most situations. TDAP is preferred to TD to provide protection against pertussis for both adolescents and adults. Both TDAP vaccines are approved by the FDA as a single booster dose in persons who have previously received a full series of 4 or 5 doses of pediatric DTAP or DTP.

The new ACIP recommendation for TDAP is simple. Persons 10 through 64 years of age who need a dose of TD for any reason should instead receive a one-time dose of TDAP if they have not yet received a dose of TDAP. Both TDAP vaccines are approved as a single booster dose among persons who have completed a series of pediatric DTAP or DTP. Technically, this means that administration of TDAP to a person who has not received a series of DTAP or DTP, or whose vaccination history is not known, is an off-label use of the vaccine. You know that we strongly discourage off-label use of any vaccine unless that use is specifically endorsed by ACIP. Fortunately, ACIP has addressed

this issue in the adolescent TDAP recommendations, and in the provisional adult recommendations. All adolescents and adults should have documentation of having received an age-appropriate series of pediatric DTAP, DTP, DT, or adult TD. Persons without documentation of this, or with an incomplete series, should receive or complete a series of three doses. The preferred schedule for persons without documentation of receiving DTP or DTAP is a single dose of TDAP, followed by a dose of TD at least 4 weeks after the TDAP dose, and a second dose of TD at least 6 months after the prior TD dose. Although this is the preferred schedule, TDAP may be substituted for any one of the 3 TD doses in the series. The recommendation for vaccination of adolescents and adults who have not received a complete series of pediatric pertussis vaccination is to administer ONE dose of TDAP. Do NOT administer two or three doses of TDAP vaccine. We must await more data and a change in the labeling of the vaccines to administer more than 1 dose of TDAP to anyone. Bill?

DR. BILL ATKINSON:

Now we would like to summarize the provisional ACIP recommendations for use of TDAP among adults. Many of the issues common to both adolescents and adults, such as the interval since the last dose of Td, contraindications and precautions, can be found in the March 2006 document. As with adolescents, a single dose of Adacel may be administered to adults 19 through 64 years of age to replace a single dose of TD. Adacel may be given at an interval less than 10 years since receipt of last tetanus toxoid-containing vaccine to protect against pertussis.

Infants younger than 12 months of age are most likely to have complications and die from pertussis. So special emphasis should be placed on TDAP vaccination of adults with close contact with infants, such as childcare and healthcare personnel, and parents and other household contacts.

ACIP struggled with recommendations for vaccination of pregnant women. On one hand, if the woman received TDAP before or during pregnancy, her passive immunity might help protect the newborn from pertussis. On the other hand there are few safety data for pregnant women given TDAP, and there are concerns by some experts that the passive pertussis antibody could interfere with the infant's response to DTAP. After extensive discussion of this issue, ACIP has recommended that because of these uncertainties, TD is generally preferred DURING pregnancy for women who need protection against tetanus and diphtheria. However, all women should receive a dose of TDAP in the immediate postpartum period-preferably before leaving the

hospital- if they have not previously received it. Any woman who might become pregnant is encouraged to receive a single dose of TDAP. However, ACIP also voted to recommend that a clinician may choose to administer TDAP to a pregnant woman in certain circumstances, such as during an outbreak of pertussis in the community. In this situation the benefit of boosting pertussis immunity outweighs the hypothetical risk for the mother or infant. Both the package inserts and the ACIP statement will state that pregnancy is not a contraindication for vaccination with TDAP.

Healthcare personnel are a high priority group for TDAP vaccination. ACIP recommends that healthcare personnel who work in hospitals or ambulatory care settings, have direct patient contact, and have not already received a dose should receive a single dose of TDAP as soon as feasible. Priority should be given to vaccination of healthcare personnel who have direct contact with infants 12 months of age and younger. This will help protect infants who may not have passive maternal antibody, and may be too young to have completed a series of DTAP vaccine. TDAP may be given at an interval as short as 2 years from the last dose of TD. Please make TDAP vaccination of your staff, and yourself, a priority. This will help protect you from an infection you do not want, and help protect your vulnerable patients as well.

Many offices are now stocking both pediatric DTAP and TDAP in the same refrigerator. Unfortunately, the packaging of both types of vaccine is similar. This has led to MANY vaccine administration errors. Pediatric DTAP has been administered to persons 7 years of age or older, and TDAP has been administered to children. This has happened so much that ACIP addressed it in the adolescent TDAP statement published in March. We do not have time on this broadcast to discuss the management of these errors- you can get that from the ACIP statement. But we would like to point out a resource to help you PREVENT these mistakes. The California Immunization Branch has produced a poster titled Check Your Vials. The poster shows images of the DTAP and TDAP brands and reminds your staff to look carefully before administration of one of these products. Vaccine administration errors are not acceptable practice. We encourage all of you to discuss this issue with your staff. And download a copy of the Check Your Vials poster from the California Immunization Branch and post it on the front of your refrigerator. We will provide a link to the poster on the broadcast updates and resources web page.

To access the most accurate and relevant health information that affects you, your family and your community, please visit [www.cdc.gov](http://www.cdc.gov)